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Arsenic in Herbal Kelp Supplements: Concentration, Regulations, and Labeling

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"Case Report: Potential Arsenic Toxicosis Secondary to Herbal Kelp Supplement" by Amster et al. (2007) is fundamentally flawed, both scientifically and with regard to the regulation of dietary supplements.

Amster et al. (2007) claimed to have found "detectable levels of arsenic in eight of the nine kelp herbal supplements, ranging from 1.59 ppm to 65.5 ppm by dry weight (1.59, 2.28, 9.55, 9.97, 10.5, 24.1, 34.8, and 65.5 ppm)," with a median of 10.23 ppm. In this instance, concentrations are irrelevant without disclosing the mass of the capsules. This would allow for calculation of the potential exposure to arsenic; any valid scientific argument on toxicity has to be based on exposure levels and daily intake, not on concentration.

For example, if we applied a 50-mg mass as the capsule mass, this would equate to arsenic concentrations of 0.0795, 0.114, 0.478, 0.499, 0.525, 1.21, 1.74, and 3.275 µg/capsule, respectively. With a serving of one capsule per day, this is well below the normal daily intake cited by Amster et al. (2007):

Nonoccupationally exposed individuals [had] an average total (inorganic and methylated) arsenic intake of 40 µg/day. U.S. dietary intake of inorganic arsenic has been estimated to range from 1 to 20 µg/day (Schoof et al. 1999).

A 500-mg capsule, in effect multiplying the daily intake 10-fold, would still result in all the products below the average daily total intake of 40 µg as cited by Amster et al. (2007).

The glaring omission of the mass of the capsules and the subsequent presentation of the data as a concentration allowed Amster et al. (2007) to provide a provocative story and headline. Once the real-world metrics are applied, however, the fog is dispersed and these numbers are obviously well within the numbers the authors cited as daily intake values. These data are no longer provocative and make it impossible for kelp supplements to be painted as "unsafe" as the authors suggested.

Amster et al. (2007) also were not diligent in researching kelp supplements, and they overlooked key references. One important oversight is the European Pharmacopoeia (2006), which contains a

monograph on kelp supplements, with guidelines on arsenic concentration in kelp. The European Pharmacopoeia sets a limit of 90 ppm total arsenic in kelp. Pharmacopoeial monographs are developed over the course of years by experts in the field. The sheer fact that this reference was not cited by Amster et al. (2007) further reveals their ignorance on the subject.

The application of the Food and Drug Administration (FDA) tolerance level for arsenic as residue in muscle meat of chicken and turkey, and in eggs (FDA 2006) in terms of concentration used by Amster et al. (2007) is also not applicable just on product mass alone. For instance, a 4-oz serving of turkey is converted to 113398.0924 mg. Therefore, a 2-ppm limit is applicable and logical based on the mass of the product. This serving of 4 oz turkey at a 2-ppm concentration would obviously result in exponentially greater exposure to arsenic (approximately 2,300 times greater) than a 50-mg kelp dietary supplement capsule at a 2-ppm concentration. To imply that there is toxicity associated with anything—be it a food, pharmaceutical, or dietary supplement—without applying the appropriate metrics is irresponsible and potentially damaging, as well as confusing, to the consumer who may benefit from that product.

In addition to the inappropriate use of metrics, Amster et al. (2007) did not differentiate between the different species of arsenic present in the kelp samples. This differentiation is significant since as the authors themselves present, "In most cases the toxic moiety is presumably trivalent arsenic in the form of inorganic arsenious acid (arsenite)." In fact, the California Clean Drinking Water Act of 1986 (California Environmental Protection Agency 1996), commonly referred to as "Proposition 65," sets limits only on inorganic arsenic compounds (oxides). This limit is set at 10 mg/day. The California Proposition 65 limit was determined by taking the no observed effect level, which is defined as "the highest level at which a chemical can be administered to an organism without any adverse effect (for example upon health, growth, development, reproductive capacity or lifetime) being observed" (California Environmental Protection Agency 1996), and then dividing by 1,000. In addition, the Food Chemicals Codex (1996) has set a limit of 3 ppm inorganic arsenic. There is no limit for total or organic arsenic compounds. The absence of blood arsenic at the

time of poisoning from the study (Amster et al. 2007) is also a relevant and questionable deficiency.

With respect to supplement regulation, supplements must be accurately labeled as mandated by the Dietary Supplement Health and Education Act of 1994 (DSHEA 1994) and actively monitored by the FDA. Regulatory action is taken when and where appropriate. The FDA, on a number of occasions, has stated that the DSHEA provides all the legislative authority needed to regulate dietary supplements. In testimony before the House of Representatives Committee on Government Reform, Robert E. Brackett (Center for Food Safety and Applied Nutrition, FDA) stated that the

FDA regulates the safety, manufacturing, and labeling of dietary supplements, while [the Federal Trade Commission] has primary responsibility for regulating the advertising of these products." (FDA 2005)

In conclusion, contrary to the viewpoint of Amster et al. (2007), dietary supplements are in fact regulated, have a well-established history of safety, and are essential to the health of the nation.

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Organic versus Inorganic Arsenic in Herbal Kelp Supplements

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Amster et al. (2007) reported findings from a case study involving a possible link between arsenic toxicity and the ingestion of a kelp-based supplement. The authors concluded that the arsenic-contaminated supplement was the likely cause of the neurologic, dermatologic, and gastrointestinal symptoms in their patient. Although the report has several methodologic shortcomings, the most serious flaw is the authors' failure to recognize that the arsenic most commonly found in seaweed and seafood products is relatively nontoxic. This is in contrast to inorganic arsenic, which has well-documented acute and chronic toxicity. Amster et al. (2007) did not discuss the possibility that the arsenic measured in the kelp supplement was in the organic form, nor did they address the great variability in toxicity among arsenic compounds. These two oversights lead to the unsupported conclusion that the arsenic found in kelp is responsible for the unique set of medical conditions observed in their patient.

Amster et al. (2007) stated that "all chemical forms of arsenic eventually produce the same toxic syndrome." In fact, the toxicologic properties of organic arsenic compounds are very different from those of inorganic arsenic. Inorganic arsenic is significantly more toxic than pentavalent arsenic compounds, arsenosugars, and arsenobetaine [Agency for Toxic Substances and Disease Registry (ATSDR) 2007b]. Arsenobetaine is a common constituent of seafood and is considered nontoxic. Interestingly, the major organic arsenic compounds in most seaweed are arsenosugars, which are still much less toxic than inorganic arsenic. For example, in an *in vitro* cytotoxicity assay, inorganic arsenic was 50 times more toxic than the trivalent arsenosugar and > 600 times more toxic than the pentavalent arsenosugar (Andrewes et al. 2004). In a recent article on speciated arsenic in seaweed, Rose et al. (2007) confirmed that inorganic arsenic levels in most varieties of seaweed are undetectable. Thus, the assumption that organic arsenic in the supplement could cause toxicity consistent with inorganic arsenic is scientifically unsupportable.

Although Amster et al. (2007) did not quantify an arsenic intake dose, they did use urinary arsenic levels to estimate exposure. They noted that normal levels of arsenic in urine are 50 µg/g creatinine (roughly equivalent to 50 µg As/L) and that their patient had an elevated urinary arsenic level of 85.5 µg/g creatinine.

According to the Agency for Toxic Substance Registry (ATSDR 2000), normal urinary arsenic levels are 50 µg/L, but only "in the absence of recent consumption of seafood." After seafood consumption, arsenic urinary levels can reach 1,000 µg/L (Vahter 1994). Thus, it is clear that 85.5 µg/g creatinine is not indicative of arsenic toxicity, particularly after known organic arsenic exposures. Many researchers have investigated the relationship between seafood consumption and urinary arsenic and have concluded that in order to make meaningful risk determinations through arsenic urine analysis, individuals should refrain from eating seafood (including seaweed) at least 4 days before testing (Foa et al. 1984; Kales et al. 2006).

Moreover, the symptoms most prominent in the patient described by Amster et al. (2007)—memory loss, alopecia, and fatigue—are not characteristic of arsenic toxicity (ATSDR 2007b; National Research Council 1999). The most sensitive non-cancer end point of arsenic exposure is the appearance of skin lesions (with very specific characteristics). Even these sensitive manifestations of chronic inorganic arsenic poisoning are not observed until lifetime exposures are hundreds of micrograms of arsenic per day (Abernathy et al. 2003).

There are several other limitations of the study by Amster et al. (2007). For example, the patient had manifestations of the conditions even before supplement use. Also, the authors did not discuss the possibility of iodine toxicity associated with the supplement ingestion. Certain comparisons the authors drew between the arsenic in the supplement and the regulatory limits are misleading. In particular, the reference to the Food and Drug Administration (FDA) food standard for arsenic of 2 ppm, which applies only to animals treated with veterinary drugs, is not relevant (ATSDR 2007a). FDA guidance recommends levels for seafood that are much higher. For example, the level of concern for total arsenic in crustaceans is 86 ppm, a concentration 10 times higher than the amount found in the kelp supplement (FDA 1993).

In conclusion, Amster et al. (2007) inappropriately relied on total arsenic data to link arsenic exposure to disease. They used their findings to comment on safety in the dietary supplement industry as a whole, implying that their results indicate that heavy metal contamination in supplements is a major health concern. Although contamination in food and dietary supplements is an issue that should be examined, their article did not inform this issue, and it obscures more significant food safety concerns that are of greater public health significance.

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Safe Use of Herbal Kelp Supplements

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In their report of a 54-year-old woman with a 2-year history of worsening alopecia, memory loss, and fatigue, Amster et al. (2007) attributed later-emerging symptoms to arsenic in a kelp-containing (*Laminaria digitata*) supplement. However, the authors failed to report that the product was used at two to four times the suggested amount, of potential significance because of the naturally occurring presence of iodine in kelp. Speciation of arsenic into organic and inorganic forms was not addressed, nor was the amount of arsenic consumed calculated from observed concentration levels. Also, there were errors in marketplace and regulatory descriptions.

The supplement was identified as Icelandic Kelp. The patient “initially took two tablets,” which was later increased to “at least four pills per day” (Amster et al. 2007). The authors overlooked the product’s label, which states that one tablet contains 225 µg iodine (150% of daily value) and recommends “one (1) tablet per day” (Nature’s Life, Larkspur, CA). This labeling conforms to the federal regulation that limits daily ingestion of kelp to an amount that provides no more than 225 µg iodine [Food and Drug Administration (FDA) 2006]. The product label also includes the following statement:

CAUTION: Do not exceed recommended dosage without first consulting your healthcare practitioner, as excess iodine may adversely affect thyroid function.

In neglecting to mention the product’s labeling and their patient’s decision to ignore it, Amster et al. (2007) excluded important information. Under federal law, supplement marketers must disclose material facts associated with use of their products. When a consumer ignores a label caution though, he or she takes on responsibility for that decision.

Intake of iodine at least four times this product’s recommended dose must be considered a potential factor in evaluating the observed symptoms. Four tablets contain 900 µg iodine, 600% of its daily value. Amster et al. (2007) noted that the patient had a “more severe presentation than would be expected” from the measured arsenic level. In fact, of the several symptoms recorded after the patient initiated use (and overdose) of the product, only four symptoms—weakness, nausea, vomiting, and possibly erythema—are identified in the presented “clinical manifestations of chronic arsenic exposure.” However, these same symptoms, as well as headache and diarrhea—also observed in this patient—are also associated with iodine toxicity (Pease 1996), albeit usually at higher doses. It would have therefore been no more or less speculative to declare that the patient had a “more severe presentation than would be expected” from the consumed iodine.

In their analysis Amster et al. (2007) did not differentiate between organic and inorganic arsenic. Arsenic is commonly found in seaweeds used as food (Rose et al. 2007). With the exception of hijiki, most arsenic found in food seaweeds is the organic form, recognized as less toxic than the inorganic form (Rose et al. 2007). The European Pharmacopoeia (European Pharmacopoeia Commission 2007) allows up to 90 ppm arsenic in kelp used in medicinal products, whereas food regulators have advised that consumption of hijiki—but not kelp or other seaweeds—be avoided due to arsenic concentrations in this species (Food Standards Agency 2004).

Although Amster et al. (2007) noted that the arsenic concentration found in most of the analyzed supplements exceeded FDA tolerances for residues in meats and eggs, they did not compare consumed arsenic from these separate sources. Daily consumption of 5 oz chicken—about one-half a chicken breast [the amount of food from the meat or beans group needed daily by women > 51 years of age, according to the U.S. Department of Agriculture’s (USDA) current food pyramid (USDA 2007)]—at the allowed arsenic concentration of 0.5 ppm would contain 71 µg arsenic. To take in the same amount of arsenic from the tested samples of Icelandic Kelp, the patient would have needed to consume between 2 g (at 34.8 ppm arsenic) and 45 g (at 1.59 ppm) of these tablets daily. Although she may have used an amount at the lower end of this range, her symptoms would be just as likely to be observed in persons eating more than half a chicken breast each day.

Financial data that Amster et al. (2007) attributed to Anonymous (2002) was misstated; sales of supplements in 2001 reached only about one-tenth of the reported \$178 billion. Additionally, the authors were apparently uninformed about differences between “homeopathic medications,” regulated as drugs since 1938, and dietary supplements, which have been placed in a specific regulatory class only since 1994. The authors’ reports of adulterated products in Singapore (Tay and Seah 1975), England (Mitchell-Heggs et al. 1990), and Brazil (Mattos et al. 2006) are irrelevant to the U.S. marketplace and its regulations, as is the citation from a 1990 reference about labeling of “botanical medicines” in light of the 1994 law (Mitchell-Heggs et al. 1990), which requires supplement labels to disclose more information than conventional food products.

In conclusion, we have no disagreement with the authors’ implication that marketers have a responsibility to control the level of potentially harmful contaminants in herbal products. Inaccurate reporting and speculative science, however, have no place in safety evaluations of case reports associated with supplements.

The authors are employees of a trade association that represents the herbal products industry; 100% of their wages are provided by companies in this trade. Some such companies sell products that contain kelp. The manufacturer of Icelandic Kelp is not a member of this trade association.

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Arsenic in Herbal Kelp Supplements: Schenker et al. Respond

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We are heartened by the feedback we have received from concerned patients, health-care professionals, herbal supplement retailers, and government health officials regarding our recent case study (Amster et al. 2007), but we certainly understand the concern from the representatives of the herbal trade industry. We would like to take this opportunity to respond to some of their comments.

In their letter, McGuffin and Dentali suggest that iodine was the cause of our patient’s symptoms, a conclusion with which we disagree. Daily intake of up to 500 µg iodine does not clinically affect the thyroid. Although it has been suggested that 1–2 mg/day is safe, there is also evidence that much higher intakes are tolerated without problems. In their comprehensive review of this subject, Backer and Hollowell (2000) concluded that “the strongest data suggest that low levels of iodine (1–5 mg/day) are safe for most people for years.” The 10th edition of the *Recommended Dietary Allowances* (National Research Council 1989) suggested a maximum allowable dietary intake of iodine of 2 mg/day for adults, and Breecher and Dworken (1986) noted that chronic toxicity

develops only when intake is > 2 mg/day. Increased iodine intake (≤ 10 mg/day) may cause hypothyroidism or hyperthyroidism, but this condition is quite rare and is usually associated with underlying risk factors such as thyroiditis, subacute thyroiditis, or previously treated Graves disease. Intake of very high concentrations (18 mg to > 1 g/day) has been associated with iodine goiter (Wolff 1969).

Although we wonder how many cases of hypothyroidism are caused by irresponsible supplement use, in our case iodine toxicity is not the most likely etiology. Our patient (Amster et al. 2007) had normal thyroid function tests on two different occasions when hypothyroidism was being considered. Furthermore, she fully recovered (especially memory loss and fatigue) within 3 weeks after discontinuation of the kelp supplement. This short span of time for recovery would most likely not occur if she had iodine-induced hypothyroidism. In summary, the clinical presentation of this case was not consistent with iodine toxicity, particularly at the dose ingested. It is our clinical opinion, given the supporting clinical history and laboratory evidence, that her symptoms were more likely from the arsenic found in her kelp supplement and not from iodine. We believe this case raises legitimate concerns about arsenic toxicosis from commercially available kelp supplements and that further testing is indicated.

McGuffin and Dentali suggest that the patient is to blame for taking more than the recommended dose. We agree that the patient has ultimate responsibility to stay within the manufacturer's guidelines, but we wonder if our patient may have been more careful in her self-prescribing if the presence of potentially toxic levels of heavy metals were included in the product labeling. This does, however, highlight a general concern of herbal medications as they are currently marketed and used: There is little oversight from prescribing health practitioners, and self-dosing commonly leads to overdosing and possible adverse herb-drug interactions (Bush et al. 2007).

McGuffin and Dentali are correct that our reporting of the dietary supplement market share was indeed misstated. We

reported \$178 billion from the *Nutrition Business Journal* (Anonymous 2002), but \$17.8 billion is the correct figure.

Our study (Amster et al. 2007) was not intended to be a comprehensive survey of arsenic content in commercial kelp supplements, but rather to call attention to the large variability of arsenic concentrations. In his letter, Lewis suggests, without documentation, that "the arsenic most commonly found in seaweed and seafood products is relatively nontoxic," that is, organic arsenic. In a recent study on arsenic content in ethanolic kelp and bladderwrack extracts, Krishna et al. (Krishna MVB, Brewer TM, Marcus RK, unpublished data) found that the majority (90–95%) of the arsenic present was inorganic arsenic, and only minor amounts of arsenic (5–10% of the total arsenic) were dimethyl arsenic acid. This finding suggests that the majority of arsenic in kelp supplements is the more toxic inorganic arsenic.

McGuffin and Dentali, representatives from the American Herbal Products Association, point out the difference between homeopathic and herbal therapies. We agree that there are differences, but for the purpose of our study there are obvious similarities: Both are used for medicinal purposes on a nonprescription basis and have been found to have toxic levels of heavy metals. McGuffin and Dentali are correct to point out that homeopathic medicines are regulated in a similar fashion to allopathic medicinals, as opposed to dietary supplements, which under the Dietary Supplement Health and Education Act of 1994 (DSHEA 1994) lack regulatory standards for premarket approval, good manufacturing standards, and labeling of indication (Borneman and Field 2006).

In conclusion, it was in no way our intention to attack the complementary alternative medicine community. Fortunately we all agree that the supplement industry has a responsibility to control the level of potentially harmful contaminants in their products. However, if the majority of certain herbal supplements have detectable levels of toxic metals—as is the case in our and other studies on kelp—then perhaps we should not leave the responsibility to the industry itself, but instead encourage our government to regulate these medicinals the same

as all other medications, and not as dietary supplements.

The authors declare they have no competing financial interests.

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CLARIFICATION

In the November Focus article ["Carbon Capture and Storage: Blue-Sky Technology or Just Blowing Smoke? *Environ Health Perspect* 115:A538–A545 (2007)], Jeff Chapman, chief executive officer of the Carbon Capture and Storage Association, suggested €62 billion as the potential annual, not cumulative, revenue from the European carbon dioxide cap-and-trade system.